

REMARKS

Status of the claims:

With the above amendments, claims 12 and 15 have been canceled, claims 1-5, 7-11 and 13 have been amended, and claims 16-17 have been added. Thus, claims 1-11, 13-14, and 16-17 are pending and ready for further action on the merits. No new matter has been added by way of the above amendments. Support for new claims 16 and 17 can be found at page 38, line 19 to page 39, line 7 of the instant written description. Support for the amendment to claim 8 can be found in original claim 12. All other amendments are merely for form and are non-narrowing in scope. Reconsideration is respectfully requested in light of the following remarks.

Claim Objections

Claims 5, 6, and 7 are objected to for being in improper multiple dependent form. Claims 5 and 7 have been amended so they are now in correct multiple dependent form. Applicants believe that with this amendment that the objection has been

obviated. Withdrawal of the objection is warranted and respectfully requested.

Rejections under 35 USC §112, first paragraph

Claims 8-14 have been rejected under 35 USC §112, first paragraph as allegedly not being enabled. The Examiner asserts that claims 8-14 are not enabled for preventing smoking.

Applicants traverse.

Applicants respectfully point out that none of claims 8-14 have the phrase "preventing smoking" in them. For this reason alone, the rejection is inapposite. Moreover, Applicants have amended the claims to more particularly recite the method for stopping smoking or moderating smoking so that the method comprises making the composition in a way that is suitable for absorption via oral mucosa. The Examiner's attention is directed to Figure 8 in the written description that shows that oral mucosa absorption of theanine shows very good results. The time for reaching maximal blood theanine concentration is shorter than it is for intestinal absorption. Thus, it should be apparent to those of skill in the art that the composition is

very effective at suppressing the craving for smoking when the composition is designed to be administered via oral mucosa. In this regard, please note Test Example 2 in the written description. For the above reasons, Applicants believe that the enablement rejection is inapposite. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §112, second paragraph

Claims 8-11 are rejected under 35 USC §112, second paragraph as allegedly being indefinite. The Examiner asserts that the word "prohibition" in the claims render them indefinite. Applicants have amended these claims to recite "stopping smoking". Accordingly, Applicants believe that this phrase can be considered neither vague nor indefinite. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §§101/112

Claim 15 has been rejected under 35 USC §112, second paragraph and under 35 USC §101 for not being a statutorily recognized form of a claim. Applicants have canceled claim 15

so the rejection is moot. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §102

Claims 1-4 are rejected under 35 USC §102(b) as being anticipated by Moroe '588 (US Patent No. 4,634,588).

Claims 1-4 are rejected under 35 USC §102(b) as being anticipated by Blum '724 (US Patent No. 6,132,724).

Applicants traverse.

Moroe '588 discloses a deodorant containing theanine that has components in it that make it effective for deodorizing. However, Moroe '588 fails to disclose a composition that is effective in suppressing the craving for smoking. Applicants respectfully point out that instant claim 1 has been amended to recite "a smoking craving suppressing composition comprising an effective amount of theanine". Accordingly, the composition is one to be applied for assistance in suppressing a craving for smoking and the composition must be effective to do so as a functional limitation upon the composition. For these reasons, Applicants believe that the rejection has been obviated.

Withdrawal of the rejection over Moroe '588 is warranted and respectfully requested.

With respect to Blum '724, Applicants also traverse. Blum '724 discloses a composition comprising theanine for the treatment of various disorders in humans. These disorders are known as RDS disorders and include smoking disorders. However, although RDS include smoking disorders, RDS disorders include many other disorders such as alcoholism, SUD, BM1, obesity, pathological gambling, carbohydrate bingeing, Tourette's Syndrome, ADHD, and many other disorders (see column 22, lines 26 to 57 in Blum '724). Theanine is simply referred to as one of a huge number of effective ingredients for a broad range of diseases. Blum '724 has no direct disclosure that theanine is useful for assistance in suppressing craving for smoking. That is, there is no specific disclosure that theanine is effective for suppressing the smoking craving. Please see *In re Petering and Fall*, 133 USPQ 275 (CCPA 1962) wherein a large genus could not be used to anticipate a species. Furthermore, Blum's composition requires at least four different effective ingredients for the treatment of RDS disorders as shown in claim 1 of Blum '724. Thus, Applicants assert that Blum '724 fails to anticipate a composition comprising a smoking craving

suppressing substance that consists essentially of theanine. For these reasons, Applicant's submit that the instant invention is novel over Blum '724. Withdrawal of the rejection is warranted and respectfully requested.

Rejections under 35 USC §103

Claims 8-15 are rejected under 35 USC §103(a) as being unpatentable over Blum '724 (US Patent No. 6,132,724).

Instant Invention

The instant invention, as recited in claim 8, relates to a method for stopping smoking or moderating smoking, comprising administering to an individual a composition comprising a smoking craving suppressing substance consisting essentially of theanine in an amount sufficient to suppress craving for smoking wherein the composition is a preparation suitable for absorption via oral mucosa.

Disclosure of Blum '724

Blum '724 discloses enhancement of attentional processing that is attained by administration of an endorphinase inhibitor or enkephalinase inhibitor and optionally, a dopamine precursor,

or a serotonin precursor, a GABA precursor, or an endorphin or enkephalinase releaser, or certain herbal compounds including Rhodiola rosea extract (Pharmaline) and/or Huperzine. These components are said to promote restoration of normal neurotransmitter function and the components combined are said to enhance the release of dopamine at the nucleus accumbens and are non-addictive. Use of the dopamine precursors L-phenylalanine, or L-tyrosine, the enkephalinase inhibitor D-phenylalanine, and/or the serotonin precursor -hydroxytryptophan and a natural acetylcholinesterase inhibitor and chromium salts (i.e. picolinate, nicotinate, etc.) are especially preferred in the invention of Blum '724, but not limited to assist in relieving symptoms associated with brain phenylalanine deficiency.

Removal of the Rejection over Blum '724

Blum '724 discloses a composition comprising theanine for the treatment of various disorders in humans. These disorders are known as RDS disorders and include smoking disorders. However, although RDS include smoking disorders, RDS disorders include many other disorders such as alcoholism, SUD, BM1, obesity, pathological gambling, carbohydrate bingeing, Tourette's Syndrome, ADHD, and many other disorders (see column

22, lines 26 to 57 in Blum '724). Theanine is simply referred to as one of a huge number of effective ingredients for a broad range of diseases. That is, there is no specific disclosure that theanine is effective for suppressing the smoking craving. Furthermore, Blum's composition requires at least four different effective ingredients for the treatment of RDS disorders as shown in claim 1 of Blum '724. Thus, Applicants assert that Blum '724 fails to teach a composition comprising a smoking craving suppressing substance that consists essentially of theanine as is claimed in instant claim 8. Thus, Applicants submit that the Examiner is "picking and choosing" to arrive at the instant invention. In other words, the Examiner appears to be using impermissible hindsight reconstruction to arrive at the instant invention. The Examiner's attention is drawn to *In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994) regarding using a large genus to render obvious a species. In *Baird*, the court found that this was impermissible. In the present instance, Blum '724 describes two large genera; one of disorders and a second of compounds for treating them. Applicants submit that choosing the intersection of a single compound to treat a single disorder from amongst the lists provided by Blum '724 is not obvious as a matter of law. For these reasons, Applicant's submit that the

instant invention is non-obvious over Blum '724. Withdrawal of the rejection is warranted and respectfully requested.

With the above remarks and amendments, it is believed that the claims, as they now stand, define patentable subject matter such that passage of the instant invention to allowance is warranted. A Notice to that effect is earnestly solicited.

If any questions remain regarding the above matters, please contact Applicant's representative, T. Benjamin Schroeder (Reg. No. 50,990), in the Washington metropolitan area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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